

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** ( Not for submission under 37 CFR 1.99)

|                        |                  |            |
|------------------------|------------------|------------|
| Application Number     |                  | 10083576   |
| Filing Date            |                  | 2002-02-27 |
| First Named Inventor   | MALKAS, Linda H. |            |
| Art Unit               | 1643             |            |
| Examiner Name          | HUFF, Sheela J.  |            |
| Attorney Docket Number | 080371.00005     |            |

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|   | 3       | 5580903       |                        | 1996-12-03 | KAZUNORI et al.                                 |  |
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|--------------------|---------|---|--------------------------|
|                    | 1       | Almendral et al, Proc. Natl. Acad. Sci., USA, 84:1575-1579(1987)  | <input type="checkbox"/> |
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|----|--|--------------------------|
| 3  | Bechtel et al, Proc. of the American Association for Cancer Research, 37:494 (1996)  | <input type="checkbox"/> |
| 4  | Brown, Breast Cancer, Hematology/Oncology Clinics of North America, 8(1):101-112 (1994)  | <input type="checkbox"/> |
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| 7  | Gabizon et al, Cancer Research, 52:891-896 (1992)  | <input type="checkbox"/> |
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| 10 | Hickey et al, Critical Reviews in Eukaryotic Gene Expression, 7(1&2):125-157 (1997)  | <input type="checkbox"/> |
| 11 | Kang et al, Carcinogenesis, 18(2):251-257 (1997)   | <input type="checkbox"/> |
| 12 | Kirpotin et al, Biochemistry, 36:66-75 (1997)  | <input type="checkbox"/> |
| 13 | Lasic et al, Science, 267:1275-1276 (1995)   | <input type="checkbox"/> |

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|----|---|--------------------------|
| 14 | Levenson et al, Cancer Research, 57:3071-3078 (1997)  | <input type="checkbox"/> |
| 15 | Lin et al, Cell Growth & Differentiation, 8:1359-1369 (1997)  | <input type="checkbox"/> |
| 16 | Lin et al, Leukemia Research, 21(6):501-512 (1997)  | <input type="checkbox"/> |
| 17 | Malkas et al, Biochemistry, 29(27):6362-6374 (1990)   | <input type="checkbox"/> |
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| 20 | Park et al, Proc. Natl. Acad. Sci., USA, 92:1327-1331 (1995)  | <input type="checkbox"/> |
| 21 | Pohl et al., Neural network evaluation of multiple tumor markers for diagnosis of ovarian cancer (Meeting Abstract), Non-serial, 3rd International Conference of the Mediterranean Society of Tumor Marker Oncology, CANCERLIT Accession No 95614997 (1994) | <input type="checkbox"/> |
| 22 | Sekowski et al, Toxicology and Applied Pharmacology, 145:268-276 (1997)   | <input type="checkbox"/> |
| 23 | Simbulan-Rosenthal et al, Biochem, 35(36):11622-11633 (1996)  | <input type="checkbox"/> |
| 24 | Soule et al, Cancer Research, 50:6075-6086 (1990)   | <input type="checkbox"/> |

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|    |   |                          |
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| 25 | Soule et al, J. of the Natl. Cancer Inst., 51(5):1409-1413 (1973)         | <input type="checkbox"/> |
| 26 | Stampfer, J. of Tissue Culture Methods, 9(2):107-115 (1985)               | <input type="checkbox"/> |
| 27 | Tait et al, Cancer Research, 50:6087-6094 (1990)                          | <input type="checkbox"/> |
| 28 | Tockman et al, Cancer Research, 52 (Suppl.):2711s-2718s (1992)            | <input type="checkbox"/> |
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| 30 | Ward, Developmental Oncology, 21:90-106 (1985)                            | <input type="checkbox"/> |
| 31 | Waseem et al, J. of Cell Science, 96(1):121-129 (1990)                    | <input type="checkbox"/> |
| 32 | Winter et al, Ann. Rev. Immunol., 12:433-455 (1994)                       | <input type="checkbox"/> |
| 33 | Sekowski et al, Cancer Res., 58:3259-3263 (1998)                          | <input type="checkbox"/> |
| 34 | Yagura et al, Biochemistry, American Chemical Society, 26:7749-7754(1987) | <input type="checkbox"/> |
| 35 | Zhigang et al, J. Biological Chemistry, 271(45):28243-28249 (1996)        | <input type="checkbox"/> |

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| 36 | Ariza et al. Env. & Mol. Mutagenesis, 27:30-33 (1996)                    | <input type="checkbox"/> |
| 37 | Coll et al, Proc. Natl. Meet. Am. Assoc. Cancer Res. 37:A3409 (1996)     | <input type="checkbox"/> |
| 38 | Lin et al, Proc. Natl. Meet. Am. Assoc. Cancer Res., 37:A3413 (1996)     | <input type="checkbox"/> |
| 39 | Malkas et al, Proc. Natl. Acad. Sci., USA, 86:70-74 (1989)               | <input type="checkbox"/> |
| 40 | Mikita et al, Biochemistry, 27:4698-4705 (1988)                          | <input type="checkbox"/> |
| 41 | Murakami et al, Proc. Natl. Acad. Sci., USA, 83:6347-6351 (1986)         | <input type="checkbox"/> |
| 42 | Roberts et al, Proc. Natl. Acad. Sci., USA, 85:7064-7068 (1988)          | <input type="checkbox"/> |
| 43 | Sekowski et al, Proc. Natl. Meet. Am. Assoc. Cancer Res., 38:A270 (1997) | <input type="checkbox"/> |

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☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

|            |                     |                     |            |
|------------|---------------------|---------------------|------------|
| Signature  | /Joseph L. Morales/ | Date (YYYY-MM-DD)   | 2007-04-28 |
| Name/Print | Joseph L. Morales   | Registration Number | 58,835     |

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